REMARKS

A Response to the Advisory Action was filed on July 21, 2010. On July 26, 2010, a supervisor at the Patent Office indicated that the term "unaffected population" may be different and suggested filing an RCE.

Claims 47-63 and 67-73 are presented for examination, with Claims 47 and 60 being currently amended. Claims 64-66 are canceled. New Claims 70 to 73 are added.

The Office Action indicated that independent Claims 68 and 69 have been allowed, and that the subject matter of dependent Claims 56 and 57 is allowable if the claims were rewritten in independent format. Both indications are acknowledged with appreciation and the claims are amended to generally comply with the suggestions.

Notably, new Claim 70 contains the subject matter of allowed Claim 69 (lesser result) and the apparatus limitations of Claim 60. Similarly, new Claim 71 contains the subject matter of allowed Claim 68 (greater result) and the apparatus limitations of Claim 60. Hence, applicants respectfully respect that allowance be extended to the apparatus Claims 70 and 71. Similarly, new Claim 72 contains the limitations of Claims 47-48 and 58, with new Claim 73 directed to the corresponding apparatus. Notably, Claim 58 is not rejected under a combination of Feldman and Kubota *et al.* Hence, Claims 72-73 are also deemed to be allowable. Support for each of the amendments is found in the previously pending claims themselves.

Further, Claims 47 and 60 are amended to clarify the population is of clinically unaffected subjects. Support for the amendments is found in the specification. See specification at p. 12, lines 25-29.

No new matter within the meaning of § 132 has been added by the amendments. Because the limitations are found in the previously pending claims, which have been

thoroughly examined, it is submitted that no additional search and consideration is required, and hence, after-final entry is respectfully requested.

35 U.S.C. § 103(a) obviousness rejections

Claims 47, 52, 60 and 63-67 were rejected as being unpatentable over U.S. 5,807,270 ("Williams") in view of JP 10000185 ("Kubota *et al.*"). The Office Action also rejected Claims 58-59 on the basis of Williams, in view of Kubota *et al.*, and further in view of U.S. 5,505,209 ("Reining"). Finally, Claims 47-55 and 60-67 were rejected on the basis of U.S. 5,788,643 ("Feldman") in view of Kubota *et al.*

In the "response to arguments" section of the previous Office Action, the Examiner noted that "a population" does not necessarily require a plurality. In response, the claims have been revised to explicitly refer to a plurality of subjects and, in particular, to refer to "the expected range for a population of clinically unaffected subjects" (emphasis added). This is described, for example, on page 12 lines 21-22 of the specification as filed.

As set out in the previous response of July 16, 2009, Kubota *et al.* does not explicitly describe a reference population formed from a plurality of unaffected subjects. In fact, a translation of Kubota *et al.*, a copy of which is provided for the Examiner's reference, makes it clear that the document only refers to a standard volume ratio being for "a healthy subject" [emphasis added] thereby explicitly restricting to the singular. See e.g., Kubota *et al.* at Claim 1, page 3, lines 31-32 and specification at [0011], p. 12, line 3.

As discussed in the previous response, Kubota *et al.* fails to teach or suggest the concept of determining if the results are outside the expected range for a population of clinically unaffected subjects, and therefore, the combination of Williams in view of Kubota *et al.* fails to establish the *prima facie* case of obviousness.

Although the Office Action that Kubota *et al.* teaches comparing a measured bioelectrical impedance value with a reference value of a population unaffected by tissue oedema, and determining if the result is outside the expected range to provide an indication of a presence or absence of tissue oedema, it is submitted that Kubota *et al.* does not describe determining if the result is outside the expected range to provide an indication of a presence or absence of tissue oedema, but rather only examines a single value (upper reference value) when performing a determination of the presence or absence of oedema. In particular, paragraph [0001] on page 6 of the translated specification of Kubota *et al.*, highlights that the invention relates to a device for determining abnormalities in body fluids, such as oedema or dehydration. The translation further clarifies in paragraphs [0013] and [0021], that the standard fluid volume ratio for the healthy individual includes an upper limit value and a lower limit value. Paragraph [0023] goes on to highlight how oedema or dehydration diagnosis subprograms are used to diagnose oedema or dehydration, respectively. When detecting oedema, the oedema subprogram compares the fluid volume ratio measure for the subject to the upper limit value only, whereas when performing dehydration analysis, the dehydration subprogram compares the fluid volume ratio to the lower limit value of the standard fluid volume ratio only. The disclosure of Kubota *et al.* also highlights, in paragraph [0025] that an oedema or dehydration diagnosis mode is selected by the operator or subject using a mode setting switch 8b. Thus, in use, the operator or subject selects whether an oedema or dehydration analysis is being performed, this in turn causes either the oedema or dehydration subprogram to be implemented. Thus, as shown in Figure 4, depending on the selection of the oedema or dehydration mode, the fluid volume ratio is then compared to a singular value, namely either the upper limit value, in the case of oedema detection, or the lower threshold value,

in the case of dehydration analysis. Hence, Kubota *et al.* clearly teaches comparing the measured fluid volume ratio to a single value (the upper limit value) only, and not to a range when analyzing for oedema.

Accordingly Kubota *et al.* does not determine the presence or absence of oedema by "determining if the result is outside the expected range for a population of clinically unaffected subjects," as presently claimed in Claim 1. This limitation is not trivial. For example, in the presently claimed invention, first and second electrical impedance measurements can be performed on a subject to compare a limb that potentially has oedema (an "at risk" limb) with a limb that potentially does not have oedema. In this case, the value of the result will depend on the order in which the measurements are processed. If a ratio of a first limb to a second limb is used as the result, the result value will depend on whether the first or second limb is the "at risk" limb. Performing a comparison to a "single" value would not take this distinction into account. However, by using a range of expected values for a plurality of unaffected subjects, the result can be compared directly to a range, taking into account that either the first or second limb may be the "at risk" limb. Because the use of a range for oedema detection is not taught by Kubota *et al.*, the applicants respectfully submit that it is also not taught or suggested by the combinations of Williams and Kubota *et al.* In view of this, the applicants respectfully submit that the revised claim is non-obvious.

Conclusion

In light of the foregoing, it is submitted that the application is now in condition for allowance. It is therefore respectfully requested that the rejection(s) be withdrawn and the application passed to issue.

Respectfully submitted,
HAHN & VOIGHT PLLC

/Roger C. Hahn/

_____

Attorney for Applicants
Roger C. Hahn
Reg. No. 46,376